Efficacy Evaluation of Health Care Personnel Handwash Products
HTR Study No. 01-109083-11

This study was performed at Hill Top Research Inc. (study # 01-109083-11) and the procedure was the current revision of ASTM E-1174-00, Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel or Consumer Handwash Formulations. The revision to the test method provides procedures to assure adequate rapid neutralization of the antimicrobial in the handwash formulation. A neutralizer was incorporated at both sampling points. Dial Complete™ Antimicrobial Foaming Healthcare Personnel Hand Wash with 0.45% Triclosan was used as the test product.

The study is designed to measure the reduction of transient microbial flora following routine hand washing with an antibacterial product. In this study a broth culture of *Serratia marcescens* ATCC 14756 was used as an artificial contaminant bacteria on the hands. Activity was measured by comparing the microbial counts of the marker organism removed after a single use of the product to the baseline number, the number of organisms recovered from the contaminated unwashed hands. Comparisons are made again following the 11th wash of a multiple wash procedure (11). Prior to each of the eleven washes the hands were artificially contaminated with *S. marcescens*.

In addition to testing Dial Complete™, Hibiclens® with 4% CHG, which is recommended by the FDA as a control, was included in this study. Enough subjects were preenrolled to ensure the required number of subjects (45) 30 for Dial Complete formula and 15 for Hibiclens, who fulfilled the study criteria. There was a one-week wash out period in which subjects refrained from using antimicrobial-containing products. On test day, subject's hands were contaminated with *S. marcescens* and a baseline sampling was performed. Following washing with the test product, treatments 1 & 11, subject's hands were sampled for post treatment count. The sampling fluid was enumerated for recovery of *S. marcescens*.

Results from the Health Care Personnel Handwash study were evaluated by comparing bacteria counts recovered from the hands following product treatment vs. the baseline counts. The bacteria counts were calculated into log counts. The log counts of each subjects left and right hand were averaged. The following $\log_{10}$ reductions were achieved:

Product Description	WASH 1	WASH 11
Dial Complete™ 3466-18	3.47	3.58*
Hibiclens® 3466-19	2.50	3.78*

* No statistical difference between the test products

HILL TOP RESEARCH, INC.

REPORT FOR

EFFICACY EVALUATION OF HEALTH CARE PERSONNEL HANDWASH PRODUCTS

HTR STUDY NO. 01-109083-11

November 12, 2001

FOR
THE DIAL CORPORATION
15101 North Scottsdale Road
Scottsdale, AZ 85254-2199

BY
HILL TOP RESEARCH, INC.
Main and Mill Streets
Miamiville, OH 45147

D00099

TABLE OF CONTENTS

APPENDICES

IMPORTANT NOTICE

1.0 SUMMARY

- The purpose of this study was to determine the ability of antimicrobial hand washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism, *Serratia marcescens* ATCC 14756.

  Forty-five subjects completed the study.

- Two test articles identified by the sponsor as 3466-18, Foaming Handwash (HTR Code A) and 3466-19, Hibiclens (HTR Code B) were evaluated in this study.

- The test article evaluated in this study, identified by the sponsor as 3466-18, Foaming Handwash (HTR Code A), achieved a 3.47 $\log_{10}$ reduction of the marker organism *Serratia marcescens* ATCC 14756 following a single 30-second handwashing procedure. After 11 repetitive washes a 3.58 $\log_{10}$ reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as 3466-19, Hibiclens (HTR Code B), achieved a 2.51 $\log_{10}$ reduction of the marker organism following a single 30-second handwashing procedure and a 3.79 $\log_{10}$ reduction of the marker organism after 11 repetitive washes.

2.0 STUDY MONITOR

Janice Fuls
The Dial Corporation

3.0 INVESTIGATIVE PERSONNEL

Investigator:	Gayle K. Mulberry, M.S.
Sub-Investigators:	Kathleen A. Baxter, B.S. Ann R. Brady, A.S.
Medical Consultant:	E. Linn Jones, M.D., D.A.B.D.
Biostatistician:	James P. Bowman, M.S.
Manager Biostatistics:	Barbara M. Fath

4.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, was reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board was obtained on July 3, 2001, prior to initiation of the investigation (see Appendix I).

This study was conducted according to applicable Good Clinical Practices and the Standard Operating Procedures of Hill Top Research, Inc.

5.0 PROTOCOL

The Study Protocol was followed (see Appendix II) with the exception of the following deviations.

- Subject 4 wet hands prior to receiving test article A on test wash #6. The protocol stated that the only time water could be added was 15 seconds after lathering with test article A, if necessary.
- Subject 2 had hands examined by the medical consultant 13 days after the study procedures were completed. The protocol stated that the subjects were to have hands examined 4 to 8 days after the study was completed.

In the opinion of the Investigator, the deviations did not compromise the integrity of the study.

6.0 SUBJECTS

Seventy-six (76) subjects were enrolled in the pre-test conditioning phase. Forty-five (45) subjects, twelve (12) males and thirty-three (33) females who met the study criteria were enrolled in the test phase and completed the study.

Thirty-one (31) subjects were excluded or withdrew from the study. The subject's screening number and reason each subject was excluded or withdrew are shown in Appendix III.

7.0 STUDY SCHEDULE

Screening/Conditioning Dates:	July 9, 2001
Date Initiated:	July 17, 2001
Date Completed:	October 29, 2001

8.0 TEST ARTICLES

The following test articles were received by Hill Top Research on July 6, 2001.

HTR Code	Sponsor Code	Description	No. of Units
A	3466-18, Foaming Handwash	White plastic bottle and pump nozzle unit containing product	10
B	3466-19, Hibiclens	Blue-green plastic bottle with white plastic cap containing liquid	1

Test articles will be returned to sponsor within one week of issuance of final report.

9.0 ADVERSE EVENTS

There were ten adverse events reported during the course of the study. (See Appendix IV).

10.0 TEST FOR ADEQUACY OF NEUTRALIZER

A report on testing performed to demonstrate the effectiveness of the antimicrobial neutralizer used in this study is shown in Appendix V.

11.0 METHOD OF STATISTICAL ANALYSIS

The data were statistically analyzed using analysis of variance methods. The statistical methods are described below.

Bacterial counts recovered from the hands were transformed into $\log_{10}$ counts. The data used in the statistical analysis were the averages of each subject's right and left-hand $\log_{10}$ counts. Analysis of variance techniques were used to evaluate the effectiveness of each treatment as a function of the number of treatments (within treatment analysis using $\log_{10}$ reductions) and to compare the baseline counts of subjects assigned to the two test articles.

Percent reductions of bacterial counts from baseline were also determined.

The test articles used in this study were HTR Code A (Lot Code 3466-18 Foaming handwash) and HTR Code B (Lot Code 3466-19 Hibiclens).

Hypothesis testing was performed at the α=0.05 level.

12.0 RESULTS OF STATISTICAL ANALYSIS

12.1 Baseline Bacterial Log Count Comparison

The source data for the baseline analysis were the average $\log_{10}$ values for the right and left hands of each subject. Potential differences among the treatment groups at baseline were examined using a one-factor analysis of variance procedure.

Mean Log_{10} Baseline Counts

HTR Code A	HTR Code B	ANOVA p-value
9.2043	9.1803	>0.5000[1]

[1] No significant difference between groups at baseline

12.0 RESULTS OF STATISTICAL ANALYSIS (CONT.)

12.2 Within-Treatment Analysis

The data (log_{10} reductions) were evaluated by analysis of variance techniques to determine the existence, if any, of significant differences between test washes for each test article. The log_{10} average differences from baseline and the p-values from the ANOVA are shown below.

HTR Code	Mean Log10 Reductions		p-value
	WASH 1	WASH 11	
HTR Code A (n=30)	3.4706	3.5839	0.0763
HTR Code B (n=15)	2.5072	3.7867	**<0.0001**[1]

[1] Significantly better antimicrobial activity after eleven test washes.

12.3 Percent Reduction of Bacterial Counts

The log reduction and percent reductions of bacterial counts and associated confidence limits are presented below.

HTR Code	Log_{10} Reduction	95% Confidence Limits		Percent Reduction	95% Confidence Limits	
		Lower	Upper		Lower	Upper
WASH 1						
HTR Code A	3.4706	3.3089	3.6322	99.97%	99.95%	99.98%
HTR Code B	2.5072	2.2877	2.7266	99.69%	99.48%	99.81%
WASH 11						
HTR Code A	3.5839	3.4182	3.7495	99.97%	99.96%	99.98%
HTR Code B	3.7867	3.6081	3.9653	99.98%	99.98%	99.99%

13.0 SUBJECT DATA COLLECTION FORMS

The Data Collection Forms for each subject selected for the study is shown in Appendix VII.

Appendix VII-A - Subjects Completing the Study
Appendix VII-B - Subjects Excluded/Withdrawn

14.0 CONCLUSION

The test article evaluated in this study, identified by the sponsor as 3466-18, Foaming Handwash (HTR Code A), achieved a 3.47 $\log_{10}$ reduction of the marker organism *Serratia marcescens* ATCC 14756 following a single 30-second handwashing procedure. After 11 repetitive washes a 3.58 $\log_{10}$ reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as 3466-19, Hibiclens (HTR Code B), achieved a 2.51 $\log_{10}$ reduction of the marker organism following a single 30-second handwashing procedure and a 3.79 $\log_{10}$ reduction of the marker organism after 11 repetitive washes.

15.0 SIGNATURE

HILL TOP RESEARCH, INC.

11-12-01

Gayle K. Mulberry, M.S. Date
Investigator

16.0 QUALITY ASSURANCE STATEMENT

This study was inspected in accordance with the Standard Operating Procedures of Hill Top Research, Inc. To assure compliance with the study protocol, the Quality Assurance Unit performed an inspection during the conduct of this study and completed an audit of the study records, and final report.

Report reviewed by:

Thomas Asplan 11/12/01

Thomas Asplan, A.A.S., B.S. Date
Auditor, Quality Assurance

APPENDIX I

Total number of pages = 12

IRB Approval Letter, Approved Consent Forms And Subject Instructions

OF

HILL TOP RESEARCH, INC.

Nancy J. Pelc, M.D., Chairman

July 3, 2001

Gayle K. Mulberry, M.S.
Hill Top Research, Inc.
Main and Mill Streets
Miamiville, OH 45147

Ref:	01-109083-11
Title:	EFFICACY EVALUATION OF HEALTH CARE PERSONNEL HANDWASH PRODUCTS
Protocol Date:	June 21, 2001
Sponsor:	The Dial Corporation

Dear Mr. Mulberry:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above referenced study by the expedited review procedure. Documents included in this review were: protocol, consent forms (2), subject instructions and safety information. Approval of this study has been granted for one year from the date of this letter.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or consent form and for any new advertisements. Serious and unexpected adverse experiences and unanticipated problems involving risk to subjects must be reported promptly to the IRB. If the study is expected to last beyond the one-year approval, you must request re-approval for continuation at least 30 days in advance of the expiration date.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR, Title 21, Parts 50 and 56.

Sincerely,

Nancy J Pelc MD 7-3-01

Nancy J. Pelc, M.D. Date
Chairman

NJP/sll

CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to measure the ability of two liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately ninety (90) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Forty-five (45) subjects are expected to complete the three-visit study.

TEST ARTICLES: One of the test articles is experimental antibacterial liquid soap product. The other test article is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject. Two of every three subjects will receive the experimental product.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will be given a kit containing non-antibacterial bar soap, shampoo, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands and wrists. If you qualify, you will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Serratia marcescens*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap

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Hill Top Research
JUL 3 2001
Approved

water and washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st wash and sampling, the hands are rinsed with tap water. Following the last sampling, your hands will be rinsed with water, washed with Hibiclens®, an antimicrobial soap and treated with alcohol, prior to leaving the lab.

After completing the treatment visit and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within four to eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. Your hands will be checked for infection by a Dermatologist trained in observing infection.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to contamination with the test bacteria. For healthy persons, the possibility of a skin infection exists; however, this possibility is remote because, (1) test bacteria are applied only to intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the applications of test article but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Stacey, Study Coordinator, at 831-3114 ext. 2324 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-513-831-3114.

IRB of
Hill Top Research
JUL 3 2001
Approved

000112

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid $80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	$0*
If you do not qualify	Visit 2	you will receive	$10.00
If you qualify but are eliminated as an extra subject	Visit 2	you will receive	$20.00
If you complete	Visit 2	you will receive	$50.00
If you complete	Visit 3	you will receive	$80.00

*No payment-kit products given.

Payments will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

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JUL 3 2001
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000113

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the study that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the study already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the above information and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

_____

Subject's Name Printed: First Middle Initial Last

_____

Subject's Signature Date

_____

Signature of Person Conducting Consent Discussion Date

SUBJECT SCREEN NO. _____
SUBJECT NO. _____

IRB of
Hill Top Research
JUL 3 2001
Approved

CONSENT FORM-2

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to assure that the materials used in the main study, for growing and counting bacteria recovered from the hands of subjects, will allow the growth of the bacteria. Approximately two (2) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. Two (2) subjects are expected to complete the one visit study.

TEST ARTICLES: One of the test articles is an experimental antibacterial liquid soap product and the other test article is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: As a participant, your hands and wrists will be washed eleven times following specific directions. Your hands will be sampled after the first and eleventh wash. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. Your hands will be removed from the bags and the solution from each bag will be taken to the laboratory. The solution collected after the 1st wash will be discarded. The solution collected after the 11th wash will be tested to determine if it can be neutralized to allow growth of bacteria, which the laboratory will add to it. Following the sampling, you will rinse your hands and forearms in tap water.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

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JUL 3 2001
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RISKS: Your hands may show a "reaction." A "reaction" could be redness, swelling, itching, cracking or peeling, or in rare cases, small blisters. It is unlikely, but possible, that a rash could develop. No risk to study participants, other than those described above as "reactions" are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might also occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

BENEFITS: You will not benefit from the applications of test article but the test results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study data. The data will be coded to protect your identity. In addition, the U.S. Food and Drug Administration (FDA), the Institutional Review Board (IRB), and foreign regulatory agencies may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Stacey, Study Coordinator, at 831-3114, ext. 2324 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1- 513-831-3114.

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Hill Top Research
JUL 3 2001
Approved

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid $10.00 for the completion of this study.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you.

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Hill Top Research
JUL 3 2001
Approved

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the test that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the test already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the above information and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

_____

Subject's Name Printed: First Middle Initial Last

_____

Subject's Signature Date

_____

Signature of Person Conducting Consent Discussion Date

SUBJECT SCREEN NO. _____

SUBJECT NO. _____

IRB of
Hill Top Research
JUL 3 2001
Approved

000118

EXHIBIT B

EVALUATION OF HEALTH CARE PERSONNEL HANDWASH
SUBJECT INSTRUCTIONS

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders and anti-dandruff hair shampoos, and do not swim in a chemically treated pool or hot tub during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE

TEST DAY

_____ Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

_____ Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab –1/2 hour.

If you have any questions regarding this study, please contact Stacey, Study Coordinator, at 831-3114 ext. 2324 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 831-3354.

IRB of
Hill Top Research
JUL 3 2001
Approved

EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "Efficacy Evaluation of Health Care Personnel Handwash Products". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens)*. Although we do not expect you to have any adverse experience as a result of participation in this study, there is a remote possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Stacey, Study Coordinator at (513) 831-3114 ext. 2324 during normal business hours (8:00 am- 5 pm) or Ann Brady at (513) 831-3354 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

_____

Date Time

Thank you for your cooperation.

IRB of
Hill Top Research
JUL 3 2001
Approved

APPENDIX II

Total number of pages = 35

Protocol

HILL TOP RESEARCH, INC.

PROJ. NO. 01-109083-11
PAGE NO. IT- 1

PROTOCOL FOR
EFFICACY EVALUATION OF
HEALTH CARE PERSONNEL HANDWASH PRODUCTS

FOR: THE DIAL CORPORATION

HTR STUDY NO.: 01-109083-11

HTR Study No.:01-109083-11

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EXHIBITS

DATA COLLECTION FORMS

1.0 INTRODUCTION

The FDA issued a tentative final monograph (Federal Register, Vol. 59, pp. 31402 to 31452, June 17, 1994) prescribing the use of a health care personnel handwash method to demonstrate the antimicrobial efficacy of cleansing products containing antimicrobial ingredients for frequent use. The method presented in the Monograph is based on an American Society for Testing Materials Standard Method for Evaluation of Health Care Personnel Handwash Formulation E1174-87 published in 1987. A revision of the ASTM Method was published in 2000 entitled Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel or Consumer Handwash Formulations, E1174-00. This protocol is aligned with a revised version of the ASTM Method.

The procedure is designed to simulate routine hand washing conducted for the purpose of reducing the level of hand contamination of health care personnel under conditions of frequent use. For this procedure a broth culture of *Serratia marcescens,* ATCC 14756, is used as an artificial contaminant bacteria on the hands. Activity is measured by comparing the number of marker bacteria removed from artificially contaminated hands after a single use of the hand washing formulation to the baseline number, the number recovered from contaminated unwashed hands. A similar comparison is made following the 11th wash of a multiple (11) wash procedure. Prior to each of the washes, the hands are artificially contaminated with the *S. marcescens*.

The method described in this protocol eliminates a shortcoming common to the Proposed Monograph version of the method. This method fails to provide procedures to assure adequate rapid neutralization of the antimicrobial in the handwash formulation. A neutralizer is only included in the hand sampling fluid used to sample the last wash and is omitted from the hand sampling fluid used to sample washes preceding the final wash. This failure to include neutralizers in the hand sampling fluid may provide data that falsely exaggerates the effectiveness of the antimicrobial handwash formulation. This issue is resolved in this protocol by requiring immediate neutralization in the hand sampling fluid at all sampling points.

2.0 OBJECTIVE

The purpose of this study is to determine the ability of antimicrobial hand-washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism.

3.0 STUDY SPONSOR AND MONITOR

The Dial Corporation
15101 North Scottsdale Road
Scottsdale, AZ 85254-2199
Telephone No.: (480) 754-6495
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REPRESENTATIVE: Janice Fuls

4.0 INVESTIGATIVE ORGANIZATION AND PERSONNEL

Hill Top Research, Inc.
Main and Mill Streets
Miamiville, Ohio 45147
Telephone No.: (513) 831-3114
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Investigator: Gayle K. Mulberry, M.S.
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Sub-Investigators: Kathleen A. Baxter, B.S.
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Medical Consultant: E. Linn Jones, M.D., D.A.B.D.

5.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, will be reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Written approval by the Board must be obtained prior to the initiation of the study.

The study will be conducted in compliance with the Good Clinical Practice Regulations, the Standard Operating Procedures of Hill Top Research, Inc., the Sponsor's protocol and protocol amendment(s).

6.0 EXPERIMENTAL DESIGN

This will be a two sample (test article) study utilizing a direct paired comparison test design of baseline bacterial populations *vs.* post treatment bacterial populations. The study will consist of a one-week pretest conditioning period and one day of treatment. Forty-five (45) subjects are expected to start and complete the study, thirty (30) using HTR Code A and fifteen (15) using HTR Code B.

7.0 STUDY MATERIAL

7.1 Test Article

HTR Code	Code and Description	
A	Test Formulation:	Foaming handwash
	Lot Code:	3466-18
	Description:	thin colorless liquid
B	Test Formulation:	Hibiclens
	Lot Code:	3466-19
	Description:	clear red liquid

7.2 Equipment

7.2.1 Colony Counter - Quebec colony counter.

7.2.2 Incubator - Any incubator capable of maintaining a temperature of 25 ± 2°C may be used.

7.2.3 Sterilizer - Any suitable steam sterilizer capable of producing the conditions of sterilization.

7.2.4 Timer (stop-clock) - One that can be read for hours, minutes and seconds.

7.2.5 Plastic Bags to Sample Hands - Low bioburden – such as Glad Food Storage Bags or equivalent, 29.2 cm x 31.8 cm. (Note: Bioburden is determined according to Hill Top Microbiology Department SOP No. 11-TOPC-20-0016A.)

7.2.6 Bacteriological Pipettes, Sterile - 10.0 mL, 5.0 mL, 2.0 mL and 1.0 mL capacity.

7.2.7 Water Dilution Bottles - Any container that can be sterilized, having a 150 to 200 mL capacity and a tight closure may be used.

7.2.8 Test Tubes and Closures - Any of suitable size.

7.2.9 Handwashing Sink - A sink of sufficient size to permit subjects to wash without touching hands to sink surface or other subjects.

7.0 STUDY MATERIAL (CONT.)

7.2 Equipment (Cont.)

7.2.10 Water faucets - located above the sink at a height, which permits the hands to be held higher than the elbow during the washing procedure.

7.2.11 Tap Water Temperature Regulator and Temperature Monitor - To monitor and regulate water temperature of 40 ± 2°C.

7.2.12 Erlenmeyer Flask - 2 L capacity for culturing test organism.

7.3 Reagents and Materials

7.3.1 Kit Products for Washout Period: non-antimicrobial bar soap and shampoo, roll on antiperspirant/deodorant, rubber gloves, and disposable poly gloves.

7.3.2 Baby San® liquid castile soap. Ecolab Inc.

7.3.3 Stripping Fluid with Neutralizer - 0.075M phosphate buffer with 0.1% Triton X-100 (dissolve 0.41 g KH_2PO_4, 10.3 g Na_2HPO_4 and 1.0 g Triton X-100 in 1-L distilled water containing an inactivator which rapidly quenches the antimicrobial activity of the test article(s). Final pH 7.8 ± 0.1. Final volume 75 ± 1.0 mL).

7.3.4 Dilution Fluid - Butterfield's phosphate buffered water (or other suitable diluent) containing an antimicrobial inactivator specific for the test formulation.

7.3.5 Plating Medium – Trypticase Soy Agar

7.3.6 Tryptic Soy Broth (BBL or Difco)

7.4 Test Microorganism

Serratia marcescens, ATCC 14756 is to be used as a marker organism.

8.0 STUDY POPULATION

An adequate number of potential subjects will be enrolled into the pre-test conditioning period in order to provide 45 subjects who fulfill the criteria described below and who complete the study. The subjects will be randomly assigned to two treatment groups, one for each test article. Subject eligibility will be based upon information provided in the Demographics/Dermatological/ Medical History Form (DCF 1) and the Inclusion/Exclusion Form (DCF 2); and completion of a written informed consent (Exhibit A).

8.0 STUDY POPULATION (CONT.)

8.1 Subject Inclusion Criteria
Subjects will be eligible for enrollment if they:

8.1.1 Are a male or female, 18 through 65 years old;
8.1.2 Have signed a written informed consent (Exhibit A);
8.1.3 Are in good health, as evidenced by response to the Demographics/Dermatological/ Medical History Form (DCF 1);
8.1.4 Have hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders;
8.1.5 Have fingernails that are clean and extend no longer than approximately one (1) mm past the nail bed;
8.1.6 Are willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and hand washing during the entire study;
8.1.7 Are willing to refrain from using anti-dandruff shampoo during the entire study;
8.1.8 Are willing to refrain from using medicated/antibacterial lotions and creams during the entire study, unless prescribed by a physician for an intercurrent illness;
8.1.9 Are willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness;
8.1.10 Are willing to refrain form using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness; and
8.1.11 Are willing to comply with all study protocol requirements.

8.2 Subject Exclusion Criteria
Subjects will not be enrolled in the study if they:

8.2.1 Are currently participating in another clinical study at this or any other facility;
8.2.2 Have participated in any type of arm or hand wash study within the past seven (7) days;
8.2.3 Have cuts, scratches, or other skin disorders on their hands or wrists;
8.2.4 Have soap, detergent, and/or perfume allergies;
8.2.5 Have eczema or psoriasis on their hands or wrists;
8.2.6 Are currently pregnant;
8.2.7 Are currently lactating;
8.2.8 Have been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an auto-immune disorder, an organ transplant, or AIDS (or HIV positive); and/or
8.2.9 Have any other medical condition, which in the opinion of the Investigator(s) would preclude participation.
8.2.10 Have artificial nails or nail tips.

8.0 STUDY POPULATION (CONT.)

8.3 Other Study Restrictions

8.3.1 Subjects should not use any other personal cleansing products.

8.3.2 Subjects should avoid chemically treated pools and hot tubs.

8.3.3 Subjects should avoid exposing their hands to harsh cleaning products, chlorine, or solvents.

9.0 SUBJECT WITHDRAWAL

After admission to the study, the subject may withdraw at any time for any reason. If possible, the reason for withdrawal will be recorded.

10.0 PROCEDURE

The study will be divided into three phases; subject enrollment period, a pre-test washout (conditioning) period of at least one week duration, and a one day test period.

10.1 Subject Qualification and Enrollment

Prospective subjects will visit the test facility to be screened for their eligibility to participate in the study. Eligibility will be based upon information provided in the Demographics/Dermatological/ Medical History Form (DCF 1) and the Inclusion/Exclusion Form (DCF 2); and completion of a written informed consent (Exhibit A). Qualified subjects will be given non-antibacterial containing soap, shampoo, roll-on-antiperspirant/deodorant, several pairs of disposable poly gloves, a pair of rubber gloves, a copy of the Subject's Study Instructions (Exhibit B). They will be instructed to use the soap, shampoo, antiperspirant/deodorant, poly gloves and rubber gloves and to follow the written instructions for the entire study period.

10.2 Washout Period

This period will last at least seven (7) days. Subjects will continue to follow the special study restrictions, use the non-antibacterial soap, shampoo, and antiperspirant/deodorant, rubber gloves and poly gloves.

10.0 PROCEDURE (CONT.)

10.3 Test Day Schedule

On the day of the test period, subjects will return to the test facility. Their hands and wrists will be re-examined to ensure that they are still free of cuts, lesions, and other skin disorders. They will also be asked if they have had any illnesses or taken any medications (proprietary or prescribed) ordered by a physician since the last visit (DCF 3). Subjects who still meet the study criteria will be eligible to continue on the study. Subjects continuing on the study will be assigned a permanent subject number.

The following outlines the schedule of procedures for the test day:

a. Subjects will wash with a mild soap for 15 seconds. (Section 10.3.1)
b. Subjects' hands will be contaminated and baseline sampling performed. (Section 10.3.2)
c. Subjects' hands treated with the test articles, each treatment preceded by hand contamination. (Section 10.3.3)
d. Following treatments 1and 11, subjects hands are sampled for post-treatment count and the *S. marcescens* in the sampling fluid enumerated. (Sections 10.3.5 and 10.3.6).
e. Following each sampling of subject's hands the hands are rinsed with warm water.
f. After the hand sampling following treatment 11, the Subjects' hands will be rinsed with water, washed with Hibiclens and treated with 70% Isopropyl Alcohol (Section 10.3.7) for at least 30 seconds and allowed to air dry.

10.3.1 Conditioning Wash

All subjects, prior to the baseline sampling perform a 15-second wash using a non-antimicrobial liquid soap, Baby San® (Section 7.3.2). This procedure, described below, removes oil and dirt and familiarizes the subjects with the treatment procedure.

10.3.1.1 Five mL of Baby San® Soap is dispensed into cupped hands and distributed over all surfaces of the hands taking care not to lose the substance.

10.3.1.2 After the material is spread, a small amount of tap water 40 ± 2°C is added, and the hands and lower third of the forearms are completely lathered for 15 seconds in a vigorous manner.

10.3.1.3 The hands and forearms are then rinsed under running tap water 40 ± 2°C for 30 seconds.

10.3.1.4 The hands are thoroughly dried with a disposable paper towel.

10.0 PROCEDURE (CONT.)

10.3.2 Baseline Bacteria Count

After completing the conditioning wash, a total volume of 4.5 mL of *S. marcescens,* ATCC 14756 suspension (Section 10.4), (minimum of 10^8 organisms per mL) is added into the subjects' cupped hands in 1.5 mL increments. After each 1.5 mL aliquot is added, the suspension is rubbed thoroughly over the surface of both hands, not going above the wrist. Each application and spreading should last approximately twenty (20) seconds. Between each aliquot the hands will be held away from the body and allowed to air dry for approximately thirty (30) seconds. Following the third 1.5mL aliquot the hands are held motionless away from the body and allowed to air dry for 90 ± 5 seconds.
(**NOTE:** The hands may not be completely dry at this time.)

Plastic bags having documented low bioburden, (Section 7.2.5) are placed on the subject's right and left hands. A 75 mL aliquot of stripping solution (Section 7.3.3) is aseptically added into each bag and the bacterial sampling procedure is carried out as described under Section 10.3.5 (Bacterial Sampling Procedure). The hands and forearms are then washed thoroughly with castile soap (Section 7.3.2) and dried.

10.3.3 Multiple Treatment Procedure

Prior to each treatment, the subject's hands will be contaminated with 4.5 mL of the *S. marcescens* suspension as described in Section 10.3.2

After completing the contamination step, the subjects perform a treatment with the assigned test article, under close supervision. The treatment procedure follows that described in the Section 10.3.4 (Method for Treating Hands). The lower third of the forearm is to be included in the wash procedure.

This procedure is repeated a total of 11 times with at least five minutes between each treatment. Immediately after completing the 1st and 11th treatments, the hands are sampled as described in Section 10.3.5 (Bacterial Sampling Procedure).

10.3.4 Method for Treating Hands

10.3.4.1 Test Article HTR Code A - Dispense two (2) pumps (3.2 mL) from the test article container into cupped palm of one hand and distribute over all surfaces of both hands. The material is worked vigorously over all surfaces of the hands and lower third of the forearm for thirty (30) seconds. (A small amount of water may be added to moisten the hands if necessary after approximately 15 seconds.) Particular attention is to be paid to the area between the fingers, beneath the nails and around the thumb. Rinse hands under running tap water for 30 seconds.

10.0 PROCEDURE (CONT.)

10.3.4.2 Test Article HTR Code B - Immediately prior to treating the hands are to be wetted with small amount of water by passing hands rapidly under the tap. Dispense 5.0 ml from a syringe into cupped palm of one hand and distribute over all surfaces of both hands. The material is worked vigorously over all surfaces of the hands and lower third of the forearm for fifteen (15) seconds. Particular attention is to be paid to the area between the fingers, beneath the nails and around the thumb. Rinse hands under running tap water for 30 seconds.

NOTE: After treatments that are not followed by a sample collection, the subjects will thoroughly dry their hand and forearms with a disposable paper towel.

10.3.5 Bacterial Sampling Procedure

Plastic bags having low bioburden (Section 7.2.5) will be placed on the subject's right and left hands. A 75 mL aliquot of stripping fluid with neutralizer (Section 7.3.3) is aseptically added into each bag. The bag on each hand is secured and massaged for one minute in a uniform manner by a lab technician. An aliquot of the fluid is aseptically obtained directly from the bagged hands within one minute of completing the massaging and immediately placed into tubes containing sterile Dilution Fluid (Section 7.3.4).

Fluid samples for bacteria counts are to be labeled by an Investigator derived code so that the individuals who prepare the plates and count the colonies are unaware of the sources of the sampling solution.

After each bacterial sampling, subjects will rinse their hands under running warm tap water 40 ± 2°C to help remove residual stripping fluid.

10.0 PROCEDURE (CONT.)

10.3.6 Bacterial Counts of Sampling Solution

Aliquots of the stripping fluid or dilutions of the fluid are spread plated in duplicate on Trypticase Soy Agar plates (Section 7.3.5).

The dilutions of the baseline sample plated represent dilutions of 10^{-4} through 10^{-6} of milliliter aliquots of the stripping fluid. The aliquots or dilutions of the treatment sample fluid plated represent dilutions of 10^{-1} through 10^{-4} milliliter aliquots of the stripping fluid.

The prepared plates are to be incubated for 48 ± 4 hours at 25 ± 2°C. Standard plate counting procedures are used to count only red pigmented colonies. The actual plate counts are recorded on the form entitled Handwash Bacterial Count Form (Data Collection Form 4).

10.3.7 Disinfection of Hands

After the final sampling is completed, subjects' hands and wrists will be rinsed with water, washed for at least sixty (60) seconds with 5mL of Hibiclens then treated for at least thirty (30) seconds with 70% Isopropyl Alcohol and allowed to air dry.

To ensure that any delayed adverse events, such as primary skin infections, are reported to the Study Investigator, all test subjects will be given a copy of Subjects' Instructions Following Study Completion (Exhibit C) before leaving the clinical site after they have completed the study. This sheet will instruct the subjects to examine their hands daily until the final scheduled visit for the presence of pimples, blisters, or raised, red itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection. Subjects, who notice such lesions, will be instructed to call the clinical test site. The subjects will return to the clinical test site within four (4) to eight (8) days after the study procedures have been completed to have their hands examined by the Medical Consultant. The Medical Consultant will complete Data Collection Form 6 for each subject on their follow-up visit.

10.0 PROCEDURE (CONT.)

10.4 Marker Organism and Preparation

S. marcescens, ATCC 14756 will be used to challenge the efficacy of the test materials.

A stock culture of *S. marcescens,* ATCC 14756 is prepared by aseptically transferring at least three isolated colonies from an agar plate to 10 mL of sterile Tryptic Soy Broth (TSB) (Section 7.3.6) which is then incubated at 25 ± 2°C for 24 ± 4 hours. A series of at least three but no more than ten 24 hour broth transfers are made in 10 mL of TSB from this broth culture. If testing occurs on multiple days, it is desired to use a test culture the same number of transfers from the source.

A 2-liter flask containing 1000 mL of TSB is inoculated with 1.0 mL of a 24-hour broth transfer. The flask is incubated for 24 ± 4 hours at 25 ± 2°C. Prior to any withdrawal of culture, whether for hand contamination or for numbers assay, the suspension is stirred or shaken. A suspension is not used for more than eight hours.

The suspension is assayed for the number of organisms at the beginning and end of the use period.

11.0 DATA EVALUATION

The number of colony forming units (CFU) recovered per sample dilution will be tabulated. The total number of CFU per mL of sampling solution will be calculated as well as the number per hand.

The data will be evaluated using parametric statistical analyses as follows:

Bacterial counts recovered from the hands will be transformed into log counts. The log count of each subjects left and right hand will be averaged. The changes from baseline counts at each sampling interval will be obtained for each test article.

An analysis of variance will be performed on the data to:
Compare baseline counts of subjects assigned different test articles.
Evaluate the effectiveness of each treatments as a function of the number of treatments (within treatment analysis).

12.0 ADVERSE EXPERIENCES

12.1 Definitions

An **Adverse Event/Experience** is any unexpected or undesirable experience occurring to a subject during a study, which may or may not be related to the test article. All adverse event/experiences will be recorded (Data Collection Form 5) and reported according to the Standard Operating Procedures of Hill Top Research, Inc.

A **Serious Adverse Drug Event/Experience** is any adverse drug experience occurring at any dose that results in any of the following outcomes:

- death;
- a life-threatening adverse drug experience;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant disability/incapacity;
- a congenital anomaly/birth defect

Important medical event/experiences that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An **Unexpected Adverse Drug Event/Experience** is any adverse drug event/ experience not listed in the current labeling for the test article or the current investigator's brochure

12.2 Follow-up

If an **Adverse Event/Experience** occurs, the subject under the direction of the Investigator (or designee), may be referred to Hill Top's consultant physician for treatment.

Serious or Unexpected Drug Event/Experience will be followed to resolution to the extent possible (e.g., medical attention by subject's primary care physician).

12.3 Notification

The sponsor will be notified of all adverse event/experiences. Any **Serious or Unexpected Adverse Drug Event/Experience** which occurs during the study must be reported promptly by the investigator to the sponsor and the reviewing IRB, where applicable, within 24-hours of the information being reported to Hill Top Research, Inc.

13.0 INTERCURRENT ILLNESS REPORTING

If a subject reports that he/she has had an intercurrent illness during the wash-out period or during the one (1) day test period, the illness and any new medication taken will be documented on DCF 3. The subject may be discontinued from the study at the discretion of the Investigator(s).

14.0 CONCOMITANT MEDICATION

If the subject has taken any medication (proprietary or prescribed) ordered by a physician, information pertaining to that medication intake will be recorded appropriately on either DCF 3 or DCF 5.

15.0 DEVIATIONS FROM PROTOCOL

Any minor deviations from the protocol, not previously agreed to by the Sponsor and Investigator(s), that occur during the conduct of the study will be documented.

16.0 REPORT

The final report will summarize the method, data and conclusions relative to the test articles and the subjects. Source data will be retained by the testing facility on microfilm. The original source data will be maintained according to the investigator's standard operating procedure. A copy of the source documents may be obtained upon request of the Study Sponsor. Copies of transcribed data will be incorporated in the report.

17.0 NOTICE

No amendments to the protocol will be permitted without approval from the Study Sponsor, Investigator and where applicable, the Institutional Review Board. Such changes will be documented in writing. Approval by the Board must be obtained prior to initiation of the amendment.

18.0 PROTOCOL APPROVAL

HILL TOP RESEARCH, INC.

By: Gayle K. Mulberry 6-21-01
Gayle K. Mulberry (Date)
Investigator

THE DIAL CORPORATION

By: Janice L Fuhr 6/26/01
(Date)

EXHIBIT A

PROJ. NO.	01-109083-11
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SAMPLE CONSENT FORM

CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to measure the ability of three liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately ninety (90) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Forty-five (45) subjects are expected to complete the three-visit study.

TEST ARTICLES: One of the test articles is experimental antibacterial liquid soap product. The other test article is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will be given a kit containing non-antibacterial bar soap, shampoo, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Serratia marcescens*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap water and

washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st wash and sampling, the hands are rinsed with tap water. Following the last sampling, your hands will be rinsed with water, washed with Hibiclens®, an antimicrobial soap and treated with alcohol, prior to leaving the lab.

After completing the treatment visit and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within four to eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. Your hands will be checked for infection by a Dermatologist trained in observing infection.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to contamination with the test bacteria. For healthy persons, the possibility of a skin infection exists; however, this possibility is remote because, (1) test bacteria are applied only to intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the applications of test article but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Stacey, Study Coordinator, at 831-3114 ext. 2324 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-513-831-3114.

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid $80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	$0*
If you do not qualify	Visit 2	you will receive	$10.00
If you qualify but are eliminated as an extra subject	Visit 2	you will receive	$20.00
If you complete	Visit 2	you will receive	$50.00
If you complete	Visit 3	you will receive	$80.00

*No payment-kit products given.

Payments will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the study that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the study already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the above information and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

_____

Subject's Name Printed: First Middle Initial Last

_____

Subject's Signature Date

_____

Signature of Person Conducting Consent Discussion Date

SUBJECT SCREEN NO. _____
SUBJECT NO. _____

CONSENT FORM-2

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to assure that the materials used in the main study, for growing and counting bacteria recovered from the hands of subjects, will allow the growth of the bacteria. Approximately two (2) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. Two (2) subjects are expected to complete the one visit study.

TEST ARTICLES: One of the test articles is an experimental antibacterial liquid soap product and the other test article is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: As a participant, your hands and wrists will be washed eleven times following specific directions. Your hands will be sampled after the first and eleventh wash. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. Your hands will be removed from the bags and the solution from each bag will be taken to the laboratory. The solution collected after massaging will then be tested to determine if it can be neutralized to allow growth of bacteria, which the laboratory will add to it. Following the sampling, you will rinse your hands and forearms in tap water.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: Your hands may show a "reaction." A "reaction" could be redness, swelling, itching, cracking or peeling, or in rare cases, small blisters. It is unlikely, but possible, that a rash could develop. No risk to study participants, other than those described above as "reactions" are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might also occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

BENEFITS: You will not benefit from the applications of test article but the test results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study data. The data will be coded to protect your identity. In addition, the U.S. Food and Drug Administration (FDA), the Institutional Review Board (IRB), and foreign regulatory agencies may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Stacey, Study Coordinator, at 831-3114, ext. 2324 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1- 513-831-3114.

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid $10.00 for the completion of this study.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you.

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the test that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the test already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the above information and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

_____

Subject's Name Printed: First Middle Initial Last

_____

Subject's Signature Date

_____

Signature of Person Conducting Consent Discussion Date

SUBJECT SCREEN NO. _____

SUBJECT NO. _____

EXHIBIT B

EVALUATION OF HEALTH CARE PERSONNEL HANDWASH
SUBJECT INSTRUCTIONS

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders and anti-dandruff hair shampoos, and do not swim in a chemically treated pool or hot tub during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE

TEST DAY

_____ Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

_____ Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab –1/2 hour.

If you have any questions regarding this study, please contact Stacey, Study Coordinator, at 831-3114 ext. 2324 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 831-3354.

EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "Efficacy Evaluation of Health Care Personnel Handwash Products". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens)*. Although we do not expect you to have any adverse experience as a result of participation in this study, there is a remote possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Stacey, Study Coordinator at (513) 831-3114 ext. 2324 during normal business hours (8:00 am- 5 pm) or Ann Brady at (513) 831-3354 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

_____

Date Time

Thank you for your cooperation.

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	___/___/___ mm dd yy	___/___/___ F M L	Permanent #:	01-109083-11

Gender: ☐ Male ☐ Female	Age: _____ Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?			
2. Eczema ?			
3. Skin Cancer ?			
4. Skin Allergies ? Please specify:			
5. Hives ?			

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.			
2. Hepatitis ?			
3. Heart and Vascular Disease?			
4. Liver Disease ?			
5. Kidney Disease ?			
6. Tuberculosis ?			
7. Diabetes ? Controlled? Diet [ ] Oral [ ] Insulin [ ]			
8. Cancer ?			
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?			
10. Organ transplant ?			
11. Any other condition not listed ? Please specify:			

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?			
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?			
3. Heart Medication ?			
4. Insulin ?			
5. Other ?			

Comments:

Based on the above medical history, the subject is: ☐ **Qualified** or ☐ **Not qualified** for the study.

erviewer's Signature:	Date: _____/_____/_____ mm dd yy

INCLUSION / EXCLUSION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	___/___/___ mm dd yy	___/___/___ F M L	Permanent #:	01-109083-11

INCLUSION CRITERIA

Check one YES	NO	Subject:
		1. Is 18 through 65 years ?
		2. Has signed informed consent ?
		3. Is healthy as evidenced by responses on DCF 1 ?
		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
		8. Is willing to refrain from using medicated/antibacterial lotions and creams during the entire study, unless prescribed by a physician for an intercurrent illness ?
		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one YES	NO	N/A	Subject:
			1. Is currently participating in another clinical study at this or any other facility ?
			2. Has participated in any type of hand or arm wash study within the past 7 days ?
			3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
			4. Has artificial nails or nail tips?
			5. Has soap, detergent, and/or perfume allergies ?
			6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? ☐ Yes ☐ No Of child-bearing potential: ☐ Yes ☐ No ☐ Surgically Sterile, year _____ ☐ Post-menopausal If of child bearing potential - β-HCG Test Results: ☐ negative ☐ positive
			8. Is currently lactating ? ☐ Yes ☐ No ☐ NA
			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, or AIDS (or HIV positive) ?
			10. Has another medical condition which in the opinion of the Investigator would preclude participation ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☐ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interveiwer's Initals/Date: _____/_____

Investigator's Signature:	Date: _____/_____/_____ mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	___/___/___ mm dd yy	___/___/___ F M L	Permanent #:	01-109083-11

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☐Yes ☐No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☐Yes ☐No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐Yes (Complete below) ☐ No

IV. Has subject used any oral or topical medication? ☐Yes (Complete below) ☐No

Based upon the above responses, the subject is: ☐Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

_____

reaction related to treatment? ☐Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

ion Taken: ☐None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

Medication taken (Complete below) ☐Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication *(Oral or Systemic)*	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication *(Reason for Taking)*
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interveiwer's Signature:	Date: ___/___/___ mm dd yy

Data Collection Form 4

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Date	Subject Initials	Subject Screen #	Study #
___/___/___ mm dd yy	___/___/___ F M L	Permanent #:	01-109083-11

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
CFU/mL _____ Counted by : _____/_____			CFU/mL _____ Counted by : _____/_____		

LEFT HAND		WASH 1			RIGHT HAND			
10^{-1*}		10^{-2}	10^{-3}	10^{-4}	10^{-1*}		10^{-2}	10^{-3}	10^{-4}
FU/mL _____ Counted by : _____/_____.					CFU/mL _____ Counted by : _____/_____.				

LEFT HAND		WASH 11			RIGHT HAND			
10^{-1*}		10^{-2}	10^{-3}	10^{-4}	10^{-1*}		10^{-2}	10^{-3}	10^{-4}
CFU/mL _____ Counted by : _____/_____.					CFU/mL _____ Counted by : _____/_____.				

Calculations by: _____/_____ Raw data reviewed by _____/_____
Calculations Verified by: _____/_____

*10^{-1} dilution is the sum of 1.0 mL spread across 3 plates in duplicate.
TNTC – Too Numerous To Count

Investigator's Signature:	Date: _____/_____/_____ mm dd yy

Data Collection Form 5A

Subject Initials ______________ Subject # __________ Study No. 01-109083-11
Page No. II - 33

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5B

Subject Initials _____ Subject #_____ Study No. 01-109083-11

Page No. II - 34

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-Ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1] Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	___/___/___ mm dd yy	___/___/___ F M L	Permanent #:	01-109083-11

Date Subject Entered the Study:	Follow-Up Visit Date:
___/___/___ mm dd yy	___/___/___ mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES ☐ NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

_____

_____

_____

Comments: _____

_____

_____

_____

Has the subject had any health related issues since the treatment procedure?

☐ YES ☐ NO If yes, complete below

Comments: _____

_____

_____

_____

Medical Consultant's Signature:		Date ___/___/___ mm dd yy

HTR-Study No. 01-109083-11

Formula Ingredient Statement

3466-18, Foaming Antimicrobial Handsoap

Active Ingredient: 0.45% Triclosan

Other Ingredients: Water (aqua), Sodium Xylenesulfonate, Dipropylene Glycol, Glycerin, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Fragrance (Parfum), Disodium Phosphate, Citric Acid, Sodium PCA, Polyquaternium-10, Cetyl Alcohol, Aloe Barbadensis Leaf Juice, Methyl-Paraben, Propyl-Paraben, Red 4, Yellow 5.

3466-19, Hibiclens

Active Ingredient: 4% Chlorhexidine gluconate

Ingredients: Fragrance, isopropyl alcohol 4%, purified water, Red 40 and other ingredients in a nonalkaline base.

APPENDIX III

Total number of pages = 1

Subjects Excluded/Withdrawn from the Study

Subjects Excluded/Withdrawn from the Study

Subject Screening No.	Reason
110, 111, 107, 120, 121, 126, 109, 145, 146, 147, 153, 160, 161, 166, 170, 172, 173, 174	Subjects withdrew prior to test day – personal reasons
114, 118, 123, 138, 149, 169, 171	Subjects excluded – cut/scratch on hand or wrist
112, 127	Subjects excluded – late on test day
137, 151, 168, 175	Subjects excluded – extra subject

APPENDIX IV

Total number of pages = 11

Adverse Events

Subject Initials EJS Subject # 2 Study No. 01-109083-11

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Cracked Pelvis	7/20/01	8/1/01	N	3	4	3	4	[signature] 9/5/01

Entry Date	Comment/Note:	Initials
7/30/01	Subject called and stated that she had been in a car accident on 7/20/01. She was admitted to a hospital for a cracked pelvis. Subject was released from the hospital on 7/26/01. Subject stated that she had no reaction on her hands & forearms.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Cracked Pelvis	7/20/01	8/1/01						

Entry Date	Comment/Note:	Initials
8/1/01	Since subject has been home, she has taken vicodin 500mg - 1000mg every 4 hours when needed for pain. Subject has also taken Tylenol PM when needed. Since the subject's accident doesn't have anything to do with the handwash study or the test article received, subject is able to get on other studies. Since she is in the a & her physici the adv is cens aspect convers with C	SEB 8/1/0

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials J-M Subject # 5

Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Papule	7-21-01	8/6/01	N	M	1	1	3*	9/5/01

Entry Date	Comment/Note: *possibly related to application of test bacteria.	Initials
7-23-01	One large (0.9cm) red papule - pustuled on the back of the right hand.	E.L.J.

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Papule	7/21/01	8/6/01						

Entry Date	Comment/Note:	Initials
8/6/01	Subject had hands looked at by a technician. His hands were clear. Subject had stated that he used neosporin a couple of times total on his hand since 7/23/01.	SBB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials BKB Subject # 7 Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Pimples	7/19/01	7/30/01	N	1	1	1	3*	9/5/01

Entry Date	Comment/Note: Possibly related to application of test bacteria. 9/5/01	Initials
7/19/01	Subject called and stated that there were many pimples and blisters on both hands. No medication was applied.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Papules	7/19/01	7/30/01						

Entry Date	Comment/Note:	Initials
7-23-01	Twelve red papules on backs of both hands	E.F.J.
7/26/01	Called subject. Subject stated that both hands were cleared up.	JCB
7/30/01	Subject's hands were checked by a technician. Hands were clear and no medication was used.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

[1]Serious Adverse Event/Experience

Subject Initials AMS Subject # 10

Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Pimples	7/19/01	10/29/01	N	1	2	1	4*	[signature] 10/31-01

Entry Date	Comment/Note: *Reactions on hands may be related to contamination with bacterial organism - Etiology of urinary infection unknown	Initials
7/19/01	Subject called and stated that there were many pimples and blisters on both hands and wrists. Subject was going to apply a triple antibiotic ointment after the phone call.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Papules	7/19/01	10/29/01	—	—	see above			[signature] 10-31-01

Entry Date	Comment/Note:	Initials
7-23-01	18 itching red papules on backs of both hands and wrists. Used antibiotic cream.	[signature]
7-31-01	Subject called the Lab. Subject stated she had 2 new papules on right hand. Not clear yet	FC

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Papules	7/19/01	10/29/01	—	—	see above			[signature] 10-31-01

Entry Date	Comment/Note:	Initials
8/2/01	Called subject. Subject went to her physician on 7/31/01 and was put on antibiotics for 5 days. Subject was on sulfamethx/trimeth 800mg/160mg 2x day since 7/31/01. Subject only took 1 pill on 7/31/01, 2 pills on 8/1/01, and 2 pills on 8/2/01. Subject will be finished with medication on 8/4/01. Subject stopped using antibiotic cream as of 8/2/01. Subject leaves for vacation for three weeks on 8/5/01. 4 papules remain on left hand and 8 papules remain on right hand. ③ Subject had stated that the reason for being on antibiotics was because the doc found something in her urine.	SEB 8/2/01

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Subject Initials AMS Subject # 10

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-Ship	Investigator Signature/Date
Papules	7/19/01	10/29/01	—	—	—	see IV/122		

Entry Date	Comment/Note:	Initials
8/13/01	Subject called and stated that one papule appeared on right hand on 8/11/01 that's about 1/4" wide and very itchy. Subject has 4 papules total remaining on right hand and left hand is basically cleared up. No medication has been applied or taken since 8/4/01. @SEB 8/13/01	SEB
8/28/01	Subject called and stated that hands were clear until one papule appeared on 8/23/01. One more papule appeared on 8/24/01 and 8/28/01.	SEB
10.29.01	Subjects hands appear clear	ARB

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials BDD Subject # 15

Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Pimples	7/18/01	7/21/01	N	1	1	1	3*	5-9-01

Entry Date	Comment/Note:	Initials
	*Possibly related to application of test organism gkn 9/5/01	
7.23.01	Subject called on 7.18.01 to let us know that she had numerous red pimples on both hands. There was no itching associated with the pimples. ABB 7.23.01	

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Pimples	7/18/01	7/21/01						

Entry Date	Comment/Note:	Initials
7/24/01	Called subject on 7/23/01. Subject stated that pimples went away as of 7/21/01. No medication was applied.	SCB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials RKG Subject # 21 Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Macules	7-21-01	8/1/01	N	1	1	1	3*	9/7/01

Entry Date	Comment/Note: *Possibly related to application of test organism	Initials
7-23-01	Six red macules on the backs of both hands.	
7/27/01	Subject called and stated that the right hand was cleared up, but the left hand has 3 macules on it still	SOB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Macules	7/21/01	8/1/01						

Entry Date	Comment/Note:	Initials
8/1/01	Subject had hands checked by a technician. Both hands were clear. No medication was applied to hands.	SOB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials L.S.B Subject # 22

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ADVERSE EVENTS

@ AE on 9/9/01

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Papules	7-21-01	7/30/01	N	1	1	1	3*	[signature] 9/9/01

Entry Date	Comment/Note: * Possibly related to application of Testosterone SEB 9/9/01	Initials
7-23-01	Twelve red papules on backs of both hands	[illegible]
7/31/01	Called subject. Subject stated that hands were cleared up.	SEB
7/30/01	Subject came to the Lab. Hands were clear. (1) No medication was used on hands. SEB 7/30/01 Hands were checked by Technician	FC

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials JLH Subject # 28 Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Papules	7-20-01	8/2/01	N	1	1	1	3*	[signature] 9/5/01

Entry Date	Comment/Note: *possibly related to application of test bacteria [signature] 9/5/01	Initials
7-23-01	Two papules on the back of the right hand	[illegible]
7/31/01	Called subject. Subject stated that papules were gone as of 7/27/01. No medication was applied.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Papules	7/20/01	8/6/01						

Entry Date	Comment/Note:	Initials
8/2/01	Subject came in to the lab to have hands checked. Hands were clear. No medication was applied.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

[1]Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials N-F Subject # 31

Study No. 01-109083-11

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Pimples	7/23/01	8/2/01	N	1	1	1	3*	E. Lindley 9/5/01

Entry Date	Comment/Note: *Possibly related to application of staff bacteria. 9/5/01	Initials
7/23/01	Subject called and stated that pimples have appeared on both hands. No medication was applied.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Papules	7/23/01	8/2/01						

Entry Date	Comment/Note:	Initials
7-24-01	Nine red papules on the backs of both hands	E.L.D.
7/27/01 remaining	Called subject. Subject stated that hands have a couple of papules on them. Subject applied aloe vera twice to hands since 7/23/01.	SEB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Papules	7/23/01	8/2/01						

Entry Date	Comment/Note:	Initials
8/2/01	Subject came into lab to have hands checked. Both hands were clear. Subject applied neosporin one time before bedtime. Subject had applied aloe vera three times total.	SEB

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definite	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Subject Initials D - M Subject # 35

Study No. 01-109083-11
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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Macules	7-20-01	7/31/01	N	1	1	1	3*	[signature] 9/4/01

Entry Date	Comment/Note:	Initials
	* Possibly related to application of test bacteria. [signature] 9/5/01.	
7-24-01	Two pink macules on a wrist and L.F. fingers.	
7/31/01	Called subject. Subject stated that both macules were gone as of 7/26/01. No medication was used. A technician checked hands. Hands were clear.	SDB

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

utcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

[1]Serious Adverse Event/Experience

APPENDIX V

Total number of pages = 4

Test for Adequacy of Neutralizer

TEST FOR ADEQUACY OF THE NEUTRALIZER

1.0 OBJECTIVE

To determine an appropriate antimicrobial neutralizer system for use in a Health Care Personnel Handwash study, HTR Study No. 01-109083-11.

2.0 TEST ARTICLES

The following test articles were received by Hill Top Research on July 6, 2001.

HTR Code	Sponsor Code	Description
A	3466-18, Foaming Handwash	White plastic bottle and pump nozzle unit containing product
B	3466-19, Hibiclens	Blue-green plastic bottle with white plastic cap containing liquid

3.0 PROCEDURE

Prior to washing with the test articles, two subjects performed a conditioning wash using Baby San Soap according to the protocol directions. The subjects then washed their hands eleven times, using either HTR Code A or HTR Code B, according to the protocol directions. The subjects' hands were sampled after treatment 1, using stripping fluid with neutralizer[1] according to the protocol directions and samples were discarded. Following the sampling after treatment 1, the subjects' hands were rinsed with tap water and dried. The subjects also dried after treatments 2 through 10 with at least five minutes elapsing between treatments. One hand was sampled after the 11^{th} treatment using stripping fluid with neutralizer. Aliquots from the subjects' stripping fluid were removed as follows and used to test the adequacy of the neutralizer: A 10.0 mL aliquot of the stripping fluid with neutralizer was removed and placed in a sterile tube. An additional 1.0 mL aliquot of the stripping fluid with neutralizer was added to a tube containing 9.0 mL of dilution fluid with neutralizer[2].

A 0.1 mL aliquot of diluted *Serratia marcescens* ATCC 14756 was added to each of the prepared tubes. The diluted culture was a 24 ± 4 hour Tryptic Soy Broth[3] culture of *S. marcescens* ATCC 14756 serially diluted to 10^{-5} in 0.9% saline[4].

3.0 PROCEDURE (CONT.)

After mixing, a 1.0 mL aliquot from each inoculated tube was surface plated immediately and again at 30 minutes by distributing the 1.0 mL across three Tryptic Soy Agar[5] plates in duplicate. The plates were incubated at 25 ± 2°C for 48 ± 4 hours. After incubation, the numbers of *S. marcescens* colony forming units were enumerated.

Number and toxicity control tubes were also prepared. The numbers control consisted of 10.0 mL 0.9% saline. Two different toxicity control tubes were prepared. One tube contained 10.0 mL stripping fluid with neutralizer and the second tube contained 10.0 mL dilution fluid with neutralizer. These control tubes were inoculated, plated, incubated, and enumerated in the same manner as the collected samples.

4.0 RESULTS

Results are shown in the Table of Results.

5.0 CONCLUSIONS

The neutralizer system is considered effective if recovery is ≥ 50% of the corresponding numbers control. In this study the neutralizer system adequately neutralized the active ingredients in the test product.

TABLES OF RESULTS
RECOVERY OF *SERRATIA MARCESCENS* ATCC 14756

ARTICLE	TIME	PLATE COUNTS*						AVG. CFU/mL	% RECOVERY
Numbers Control	0 min.	61	52	65	59	53	55	1.7×10^2	NA**
10.0 mL Saline	30 min.	48	41	72	47	62	52	1.6×10^2	NA
Toxicity Control									
10.0 mL Dilution	0 min.	54	52	51	53	66	50	1.6×10^2	94
Fluid with Neut.	30 min.	41	53	65	42	62	49	1.6×10^2	100
Toxicity Control									
10.0 mL									
Stripping Fluid	0 min.	39	43	52	40	52	48	1.4×10^2	82
with Neut.	30 min.	60	54	55	57	51	63	1.7×10^2	106
HTR Code A									
10. mL Stripping	0 min.	59	61	40	59	64	52	1.7×10^2	100
Fluid with Neut.	30 min.	64	49	63	53	60	63	1.8×10^2	112
HTR Code A									
1.0 mL Stripping									
Fluid w/ Neut.									
Into 9.0 mL									
Dilution Fluid w/	0 min.	39	47	37	35	56	46	1.3×10^2	76
Neut.	30 min.	44	55	56	45	52	50	1.5×10^2	94
HTR Code B									
10.0 mL									
Stripping Fluid w/	0min.	57	44	67	57	71	45	1.7×10^2	100
Neut.	30 min.	44	53	40	56	49	66	1.5×10^2	94
HTR Code B									
1.0 mL Stripping									
Fluid w/ Neut.									
Into 9.0 mL									
Dilution Fluid w/	0min.	52	46	46	59	63	74	1.7×10^2	100
Neut.	30 min.	37	47	47	44	54	42	1.4×10^2	88

*CFU/mL is the sum of 1.0 mL spread across three plates.

**NA = Not Applicable

$$\text{0 Minute \% Recovery} = \frac{\text{Count at 0 min.}}{\text{Numbers Control Count at 0 min.}} \times 100$$

$$\text{30 Minute \% Recovery} = \frac{\text{Count at 30 min.}}{\text{Numbers Control Count at 30 min.}} \times 100$$

REFERENCES

1. **Stripping Fluid with Neutralizer**
The stripping fluid with neutralizer used for sampling contained 0.41 g KH_2PO_4, 10.3 g Na_2HPO_4, 3.0 g Lecithin, 10.0g Tween 80, and 1.0 g Triton X-100 in one liter purified water. The pH was adjusted to 7.8 ± 0.1 prior to dispensing into water dilution bottles, or other suitable containers, to yield a final volume of 75 ± 1.0 mL after autoclaving at 121°C.

2. **Dilution Fluid: Butterfield's Phosphate Buffer Water with Neutralizer**
The dilution fluid contained 1.25 mL AOAC Phosphate Buffer Stock*, 10.0 g Tween 80, and 3.0 g Lecithin in one liter purified water. The pH was adjusted to 7.2 ± 0.2 prior to dispensing into tubes, to yield a final volume of 9.0 ± 0.1 mL after autoclaving at 121°C.

3. **Tryptic Soy Broth**
The broth consisted of 30.0 g Tryptic Soy Broth powder in one liter purified water. The pH was 7.3 ± 0.2. The media was dispensed into tubes and sterilized by autoclaving at 121°C.

4. **0.9% Saline**
The saline contained 9.0 g NaCl in one liter purified water. The material was dispensed into tubes to yield a final volume of 9.0 ± 0.1 mL after autoclaving at 121°C.

5. **Tryptic Soy Agar**
The plating medium contained 40.0 g Tryptic Soy Agar powder in one liter purified water. The pH was 7.3 ± 0.2. The media was autoclaved at 121°C. After autoclaving and tempering, the media was aseptically dispensed into sterile Petri dishes, approximately 18 - 20 mL per plate.

*The AOAC Phosphate Buffer Stock contained 34.0 g KH_2PO_4 in one liter purified water. The pH was adjusted to 7.2 ± 0.1 prior to dispensing into bottles, to yield a final volume of approximately 100 mL after autoclaving at 121°C.

Note: Recipes which are given as liter volumes may be prepared in greater or lesser volumes.

APPENDIX VI

Total number of pages = 19

Statistical Tables

Table 1	Summary of CFU counts and log conversions
Table 2A	Mean summary of log_{10} averages
Table 2B	Mean summary of log_{10} average reductions
Table 3	Means summary of log_{10} reductions from baseline, percent microbial reductions, and confidence limits
Table 4	Analysis of variance comparison of test article log_{10} baseline counts (using the average of left and right hands)
Table 5	Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments

HTR Study No.: 01-109083-11

Table 1. Summary of CFU counts and log conversions.

HTR Code=A: 3466-18 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
4	Baseline	2.3E7	1.7E+09	9.2368	3.3E7	2.5E+09	9.3936	9.3152	.
	Wash 1	8.4E3	6.3E+05	5.7993	1.5E4	1.1E+06	6.0512	5.9252	3.3899
	Wash 11	9.3E3	7.0E+05	5.8435	1.1E4	8.3E+05	5.9165	5.8800	3.4352
6	Baseline	2.5E7	1.9E+09	9.2730	2.4E7	1.8E+09	9.2553	9.2641	.
	Wash 1	6.5E3	4.9E+05	5.6880	2.8E3	2.1E+05	5.3222	5.5051	3.7590
	Wash 11	2.2E3	1.7E+05	5.2175	2.9E3	2.2E+05	5.3375	5.2775	3.9867
7	Baseline	5.2E6	3.9E+08	8.5911	7.0E6	5.3E+08	8.7202	8.6556	.
	Wash 1	2.2E3	1.7E+05	5.2175	1.3E3	9.8E+04	4.9890	5.1032	3.5524
	Wash 11	3.7E3	2.8E+05	5.4433	1.3E3	9.8E+04	4.9890	5.2161	3.4395
9	Baseline	2.1E7	1.6E+09	9.1973	2.4E7	1.8E+09	9.2553	9.2263	.
	Wash 1	5.8E4	4.4E+06	6.6385	3.2E4	2.4E+06	6.3802	6.5094	2.7169
	Wash 11	4.0E4	3.0E+06	6.4771	1.5E4	1.1E+06	6.0512	6.2641	2.9621
10	Baseline	3.2E7	2.4E+09	9.3802	2.8E7	2.1E+09	9.3222	9.3512	.
	Wash 1	2.2E4	1.7E+06	6.2175	1.5E4	1.1E+06	6.0512	6.1343	3.2169
	Wash 11	1.4E4	1.1E+06	6.0212	1.4E4	1.1E+06	6.0212	6.0212	3.3300
11	Baseline	3.0E7	2.3E+09	9.3522	2.8E7	2.1E+09	9.3222	9.3372	.
	Wash 1	1.0E4	7.5E+05	5.8751	2.6E4	2.0E+06	6.2900	6.0825	3.2547
	Wash 11	7.0E3	5.3E+05	5.7202	2.1E4	1.6E+06	6.1973	5.9587	3.3785
13	Baseline	2.5E7	1.9E+09	9.2730	2.7E7	2.0E+09	9.3064	9.2897	.
	Wash 1	3.1E3	2.3E+05	5.3664	3.6E3	2.7E+05	5.4314	5.3989	3.8908
	Wash 11	1.3E3	9.8E+04	4.9890	7.4E2	5.6E+04	4.7443	4.8666	4.4231
14	Baseline	1.5E7	1.1E+09	9.0512	2.0E7	1.5E+09	9.1761	9.1136	.
	Wash 1	6.2E3	4.7E+05	5.6675	1.2E4	9.0E+05	5.9542	5.8108	3.3028
	Wash 11	2.5E3	1.9E+05	5.2730	4.7E3	3.5E+05	5.5472	5.4101	3.7035
15	Baseline	2.2E7	1.7E+09	9.2175	2.4E7	1.8E+09	9.2553	9.2364	.
	Wash 1	2.4E4	1.8E+06	6.2553	3.2E4	2.4E+06	6.3802	6.3177	2.9186
	Wash 11	1.7E4	1.3E+06	6.1055	1.3E4	9.8E+05	5.9890	6.0473	3.1891
16	Baseline	1.7E7	1.3E+09	9.1055	2.0E7	1.5E+09	9.1761	9.1408	.
	Wash 1	1.0E4	7.5E+05	5.8751	2.5E3	1.9E+05	5.2730	5.5740	3.5668
	Wash 11	9.4E3	7.1E+05	5.8482	1.1E3	8.3E+04	4.9165	5.3823	3.7585
18	Baseline	2.5E7	1.9E+09	9.2730	2.7E7	2.0E+09	9.3064	9.2897	.
	Wash 1	4.1E3	3.1E+05	5.4878	3.2E3	2.4E+05	5.3802	5.4340	3.8557
	Wash 11	2.7E3	2.0E+05	5.3064	1.5E3	1.1E+05	5.0512	5.1788	4.1109
19	Baseline	2.2E7	1.7E+09	9.2175	2.7E7	2.0E+09	9.3064	9.2620	.
	Wash 1	2.6E3	2.0E+05	5.2900	1.2E3	9.0E+04	4.9542	5.1221	4.1398
	Wash 11	2.0E3	1.5E+05	5.1761	3.2E3	2.4E+05	5.3802	5.2782	3.9838
20	Baseline	2.6E7	2.0E+09	9.2900	1.8E7	1.4E+09	9.1303	9.2102	.
	Wash 1	2.8E4	2.1E+06	6.3222	4.2E3	3.2E+05	5.4983	5.9103	3.2999
	Wash 11	5.6E3	4.2E+05	5.6232	2.5E3	1.9E+05	5.2730	5.4481	3.7621
22	Baseline	1.6E7	1.2E+09	9.0792	1.6E7	1.2E+09	9.0792	9.0792	.
	Wash 1	1.7E3	1.3E+05	5.1055	1.7E3	1.3E+05	5.1055	5.1055	3.9737
	Wash 11	2.2E3	1.7E+05	5.2175	4.6E3	3.5E+05	5.5378	5.3777	3.7015
23	Baseline	1.3E7	9.8E+08	8.9890	1.5E7	1.1E+09	9.0512	9.0201	.

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Table 1. Summary of CFU counts and log conversions.

HTR Code=A: 3466-18 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
23	Wash 1	1.9E3	1.4E+05	5.1538	7.9E3	5.9E+05	5.7727	5.4633	3.5568
	Wash 11	1.3E3	9.8E+04	4.9890	4.8E3	3.6E+05	5.5563	5.2727	3.7474
26	Baseline	2.3E7	1.7E+09	9.2368	2.4E7	1.8E+09	9.2553	9.2460	.
	Wash 1	3.6E3	2.7E+05	5.4314	1.6E3	1.2E+05	5.0792	5.2553	3.9908
	Wash 11	6.6E3	5.0E+05	5.6946	6.8E3	5.1E+05	5.7076	5.7011	3.5449
27	Baseline	1.6E7	1.2E+09	9.0792	2.0E7	1.5E+09	9.1761	9.1276	.
	Wash 1	8.8E3	6.6E+05	5.8195	4.4E4	3.3E+06	6.5185	6.1690	2.9586
	Wash 11	2.7E4	2.0E+06	6.3064	1.2E5	9.0E+06	6.9542	6.6303	2.4973
29	Baseline	2.3E7	1.7E+09	9.2368	2.0E7	1.5E+09	9.1761	9.2064	.
	Wash 1	1.7E4	1.3E+06	6.1055	9.4E3	7.1E+05	5.8482	5.9768	3.2296
	Wash 11	2.6E3	2.0E+05	5.2900	2.0E3	1.5E+05	5.1761	5.2331	3.9734
30	Baseline	2.5E7	1.9E+09	9.2730	3.0E7	2.3E+09	9.3522	9.3126	.
	Wash 1	7.5E3	5.6E+05	5.7501	9.0E3	6.8E+05	5.8293	5.7897	3.5229
	Wash 11	1.3E4	9.8E+05	5.9890	7.8E3	5.9E+05	5.7672	5.8781	3.4345
31	Baseline	2.2E7	1.7E+09	9.2175	2.0E7	1.5E+09	9.1761	9.1968	.
	Wash 1	2.9E3	2.2E+05	5.3375	5.2E3	3.9E+05	5.5911	5.4643	3.7325
	Wash 11	3.2E3	2.4E+05	5.3802	4.6E3	3.5E+05	5.5378	5.4590	3.7378
32	Baseline	1.6E7	1.2E+09	9.0792	1.4E7	1.1E+09	9.0212	9.0502	.
	Wash 1	2.6E3	2.0E+05	5.2900	3.2E3	2.4E+05	5.3802	5.3351	3.7151
	Wash 11	1.9E3	1.4E+05	5.1538	2.7E3	2.0E+05	5.3064	5.2301	3.8201
33	Baseline	2.5E7	1.9E+09	9.2730	2.0E7	1.5E+09	9.1761	9.2245	.
	Wash 1	2.6E4	2.0E+06	6.2900	7.1E4	5.3E+06	6.7263	6.5082	2.7164
	Wash 11	2.0E4	1.5E+06	6.1761	5.2E4	3.9E+06	6.5911	6.3836	2.8410
38	Baseline	2.2E7	1.7E+09	9.2175	2.4E7	1.8E+09	9.2553	9.2364	.
	Wash 1	4.9E2	3.7E+04	4.5653	5.6E2	4.2E+04	4.6232	4.5943	4.6421
	Wash 11	4.6E3	3.5E+05	5.5378	1.5E3	1.1E+05	5.0512	5.2945	3.9419
39	Baseline	2.4E7	1.8E+09	9.2553	2.6E7	2.0E+09	9.2900	9.2727	.
	Wash 1	1.7E4	1.3E+06	6.1055	3.5E4	2.6E+06	6.4191	6.2623	3.0103
	Wash 11	4.5E4	3.4E+06	6.5283	5.8E4	4.4E+06	6.6385	6.5834	2.6893
40	Baseline	2.2E7	1.7E+09	9.2175	2.0E7	1.5E+09	9.1761	9.1968	.
	Wash 1	9.8E3	7.4E+05	5.8663	6.2E3	4.7E+05	5.6675	5.7669	3.4299
	Wash 11	3.4E3	2.6E+05	5.4065	2.8E3	2.1E+05	5.3222	5.3644	3.8324
41	Baseline	2.2E7	1.7E+09	9.2175	1.9E7	1.4E+09	9.1538	9.1856	.
	Wash 1	3.0E4	2.3E+06	6.3522	1.5E4	1.1E+06	6.0512	6.2017	2.9840
	Wash 11	1.0E4	7.5E+05	5.8751	6.3E3	4.7E+05	5.6744	5.7747	3.4109
42	Baseline	2.4E7	1.8E+09	9.2553	2.6E7	2.0E+09	9.2900	9.2727	.
	Wash 1	9.8E3	7.4E+05	5.8663	2.8E4	2.1E+06	6.3222	6.0943	3.1784
	Wash 11	9.0E3	6.8E+05	5.8293	2.0E4	1.5E+06	6.1761	6.0027	3.2700
43	Baseline	2.1E7	1.6E+09	9.1973	2.4E7	1.8E+09	9.2553	9.2263	.
	Wash 1	5.7E3	4.3E+05	5.6309	3.9E3	2.9E+05	5.4661	5.5485	3.6777
	Wash 11	4.1E3	3.1E+05	5.4878	6.3E3	4.7E+05	5.6744	5.5811	3.6452
44	Baseline	2.0E7	1.5E+09	9.1761	2.4E7	1.8E+09	9.2553	9.2157	.
	Wash 1	5.1E3	3.8E+05	5.5826	7.6E3	5.7E+05	5.7559	5.6693	3.5464

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Table 1. Summary of CFU counts and log conversions.

HTR Code=A: 3466-18 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
44	Wash 11	7.6E2	5.7E+04	4.7559	1.8E3	1.4E+05	5.1303	4.9431	4.2726
45	Baseline	3.6E7	2.7E+09	9.4314	2.7E7	2.0E+09	9.3064	9.3689	.
	Wash 1	7.4E3	5.6E+05	5.7443	2.2E4	1.7E+06	6.2175	5.9809	3.3880
	Wash 11	4.0E3	3.0E+05	5.4771	1.0E4	7.5E+05	5.8751	5.6761	3.6928

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Table 1. Summary of CFU counts and log conversions.

HTR Code=B: 3466-19 Hibiclens

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
1	Baseline	2.1E7	1.6E+09	9.1973	2.4E7	1.8E+09	9.2553	9.2263	.
	Wash 1	3.0E5	2.3E+07	7.3522	3.3E5	2.5E+07	7.3936	7.3729	1.8534
	Wash 11	2.5E3	1.9E+05	5.2730	2.6E3	2.0E+05	5.2900	5.2815	3.9448
2	Baseline	2.4E7	1.8E+09	9.2553	3.5E7	2.6E+09	9.4191	9.3372	.
	Wash 1	9.8E4	7.4E+06	6.8663	1.3E5	9.8E+06	6.9890	6.9276	2.4096
	Wash 11	6.1E3	4.6E+05	5.6604	1.1E4	8.3E+05	5.9165	5.7884	3.5488
3	Baseline	2.1E7	1.6E+09	9.1973	2.2E7	1.7E+09	9.2175	9.2074	.
	Wash 1	8.5E4	6.4E+06	6.8045	7.8E4	5.9E+06	6.7672	6.7858	2.4216
	Wash 11	8.5E3	6.4E+05	5.8045	2.2E3	1.7E+05	5.2175	5.5110	3.6964
5	Baseline	2.2E7	1.7E+09	9.2175	1.9E7	1.4E+09	9.1538	9.1856	.
	Wash 1	2.7E4	2.0E+06	6.3064	2.6E4	2.0E+06	6.2900	6.2982	2.8874
	Wash 11	4.4E3	3.3E+05	5.5185	2.4E3	1.8E+05	5.2553	5.3869	3.7988
8	Baseline	2.6E7	2.0E+09	9.2900	2.9E7	2.2E+09	9.3375	9.3137	.
	Wash 1	1.7E5	1.3E+07	7.1055	3.1E5	2.3E+07	7.3664	7.2360	2.0778
	Wash 11	1.7E4	1.3E+06	6.1055	1.4E4	1.1E+06	6.0212	6.0633	3.2504
12	Baseline	2.4E7	1.8E+09	9.2553	2.5E7	1.9E+09	9.2730	9.2641	.
	Wash 1	4.4E4	3.3E+06	6.5185	5.6E4	4.2E+06	6.6232	6.5709	2.6933
	Wash 11	2.3E3	1.7E+05	5.2368	1.2E3	9.0E+04	4.9542	5.0955	4.1686
17	Baseline	1.1E7	8.3E+08	8.9165	1.0E7	7.5E+08	8.8751	8.8958	.
	Wash 1	6.2E4	4.7E+06	6.6675	7.4E4	5.6E+06	6.7443	6.7059	2.1899
	Wash 11	4.0E3	3.0E+05	5.4771	1.4E3	1.1E+05	5.0212	5.2492	3.6466
21	Baseline	2.7E7	2.0E+09	9.3064	2.7E7	2.0E+09	9.3064	9.3064	.
	Wash 1	5.7E4	4.3E+06	6.6309	4.8E4	3.6E+06	6.5563	6.5936	2.7128
	Wash 11	7.4E3	5.6E+05	5.7443	1.1E4	8.3E+05	5.9165	5.8304	3.4761
24	Baseline	1.4E7	1.1E+09	9.0212	1.7E7	1.3E+09	9.1055	9.0633	.
	Wash 1	2.5E4	1.9E+06	6.2730	8.2E4	6.2E+06	6.7889	6.5309	2.5324
	Wash 11	7.0E2	5.3E+04	4.7202	2.8E3	2.1E+05	5.3222	5.0212	4.0422
25	Baseline	1.9E7	1.4E+09	9.1538	1.9E7	1.4E+09	9.1538	9.1538	.
	Wash 1	6.6E4	5.0E+06	6.6946	3.8E4	2.9E+06	6.4548	6.5747	2.5791
	Wash 11	2.6E3	2.0E+05	5.2900	2.6E3	2.0E+05	5.2900	5.2900	3.8638
28	Baseline	2.6E7	2.0E+09	9.2900	3.0E7	2.3E+09	9.3522	9.3211	.
	Wash 1	1.8E4	1.4E+06	6.1303	1.0E4	7.5E+05	5.8751	6.0027	3.3184
	Wash 11	1.6E3	1.2E+05	5.0792	1.1E3	8.3E+04	4.9165	4.9978	4.3233
34	Baseline	2.4E7	1.8E+09	9.2553	2.4E7	1.8E+09	9.2553	9.2553	.
	Wash 1	6.8E4	5.1E+06	6.7076	3.6E4	2.7E+06	6.4314	6.5695	2.6858
	Wash 11	4.2E3	3.2E+05	5.4983	1.6E3	1.2E+05	5.0792	5.2887	3.9665
35	Baseline	1.1E7	8.3E+08	8.9165	1.0E7	7.5E+08	8.8751	8.8958	.
	Wash 1	8.8E4	6.6E+06	6.8195	2.7E4	2.0E+06	6.3064	6.5630	2.3328
	Wash 11	2.7E3	2.0E+05	5.3064	2.5E3	1.9E+05	5.2730	5.2897	3.6060
36	Baseline	1.9E7	1.4E+09	9.1538	1.6E7	1.2E+09	9.0792	9.1165	.
	Wash 1	1.1E5	8.3E+06	6.9165	3.5E5	2.6E+07	7.4191	7.1678	1.9487
	Wash 11	8.9E3	6.7E+05	5.8245	8.8E3	6.6E+05	5.8195	5.8220	3.2945
37	Baseline	2.2E7	1.7E+09	9.2175	1.7E7	1.3E+09	9.1055	9.1615	.

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Table 1. Summary of CFU counts and log conversions.

HTR Code=B: 3466-19 Hibiclens

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
37	Wash 1	2.0E4	1.5E+06	6.1761	2.2E4	1.7E+06	6.2175	6.1968	2.9647
	Wash 11	1.2E3	9.0E+04	4.9542	1.4E3	1.1E+05	5.0212	4.9877	4.1738

Table 2a. Mean summary of log10 averages.

		Log10 Average	Std. Dev.	N
HTR Code				
A: 3466-18 Foaming Handwash	Baseline	9.2043	0.1338	30
	Wash 1	5.7338	0.4608	30
	Wash 11	5.6205	0.4604	30
B: 3466-19 Hibiclens	Baseline	9.1803	0.1400	15
	Wash 1	6.6731	0.3795	15
	Wash 11	5.3936	0.3388	15

Table 2b. Mean summary of log10 average reductions.

		Log10 Average Reductions from Baseline	Std. Dev.	N
HTR Code				
A: 3466-18 Foaming Handwash	Wash 1	3.4706	0.4329	30
	Wash 11	3.5839	0.4437	30
B: 3466-19 Hibiclens	Wash 1	2.5072	0.3963	15
	Wash 11	3.7867	0.3225	15

Table 3. Means summary of the log10 reductions from baseline, percent microbial reductions, and confidence limits.

		Confidence Interval			Confidence Interval		
		Average Log10 Difference	Log10 Lower Limit	Log10 Upper Limit	Percent Reduction	Percent Lower Limit	Percent Upper Limit
HTR Code							
A: 3466-18 Foaming Handwash	Wash 1	3.4706	3.3089	3.6322	99.97	99.95	99.98
	Wash 11	3.5839	3.4182	3.7495	99.97	99.96	99.98
B: 3466-19 Hibiclens	Wash 1	2.5072	2.2877	2.7266	99.69	99.48	99.81
	Wash 11	3.7867	3.6081	3.9653	99.98	99.98	99.99

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Class Level Information

Class	Levels	Values
HTRCode	2	HTR Code A HTR Code B

Number of observations 45

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Dependent Variable: lgavg

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.00580320	0.00580320	0.31	0.5780
Error	43	0.79395641	0.01846410		
Corrected Total	44	0.79975961			

R-Square	Coeff Var	Root MSE	lgavg Mean
0.007256	1.477577	0.135883	9.196318

Source	DF	Type I SS	Mean Square	F Value	Pr > F
HTRCode	1	0.00580320	0.00580320	0.31	0.5780

Source	DF	Type III SS	Mean Square	F Value	Pr > F
HTRCode	1	0.00580320	0.00580320	0.31	0.5780

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Level of HTRCode	N	lgavg Mean	lgavg Std Dev
HTR Code A	30	9.20434809	0.13384740
HTR Code B	15	9.18025826	0.14000453

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

---------- HTRCode=HTR Code A ----------

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	30	4 6 7 9 10 11 13 14 15 16 18 19 20 22 23 26 27 29 30 31 32 33 38 39 40 41 42 43 44 45
eval	2	Wash 1 Wash 11

Number of observations 60

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

HTRCode=HTR Code A

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	30	9.68443554	0.32281452	5.67	<.0001
Error	29	1.65181967	0.05695930		
Corrected Total	59	11.33625521			

R-Square	Coeff Var	Root MSE	lgdiff Mean
0.854289	6.766273	0.238661	3.527222

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	29	9.49195323	0.32730873	5.75	<.0001
eval	1	0.19248232	0.19248232	3.38	0.0763

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	29	9.49195323	0.32730873	5.75	<.0001
eval	1	0.19248232	0.19248232	3.38	0.0763

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

HTRCode=HTR Code A

The GLM Procedure

Level of eval	N	lgdiff Mean	lgdiff Std Dev
Wash 1	30	3.47058227	0.43288302
Wash 11	30	3.58386137	0.44371198

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

---------- HTRCode=HTR Code A ----------

The GLM Procedure

Level of eval	N	lgdiff Mean	lgdiff Std Dev
Wash 1	30	3.47058227	0.43288302
Wash 11	30	3.58386137	0.44371198

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

---------- HTRCode=HTR Code B ----------

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	15	1 2 3 5 8 12 17 21 24 25 28 34 35 36 37
eval	2	Wash 1 Wash 11

Number of observations 30

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

HTRCode=HTR Code B

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	15	15.28292052	1.01886137	21.95	<.0001
Error	14	0.64996330	0.04642595		
Corrected Total	29	15.93288383			

R-Square	Coeff Var	Root MSE	lgdiff Mean
0.959206	6.846881	0.215467	3.146934

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	14	3.00403184	0.21457370	4.62	0.0035
eval	1	12.27888868	12.27888868	264.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	14	3.00403184	0.21457370	4.62	0.0035
eval	1	12.27888868	12.27888868	264.48	<.0001

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

---------- HTRCode=HTR Code B ----------

The GLM Procedure

Level of eval	N	lgdiff Mean	lgdiff Std Dev
Wash 1	15	2.50717129	0.39625882
Wash 11	15	3.78669666	0.32245713

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Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

HTRCode=HTR Code B

The GLM Procedure

Level of eval	N	lgdiff Mean	lgdiff Std Dev
Wash 1	15	2.50717129	0.39625882
Wash 11	15	3.78669666	0.32245713